

SEP 27 2012

Section 5. 510(k) Summary

510(k) Owner:	Providence Medical Technology, Inc. 201 Spear Street, Suite 1310 San Francisco, CA. 94105 T: 415-923-9376 F: 415-923-9377
Contact Person:	Glen Mangseth gmangseth@providencemt.com T: 415-923-9376
Date Summary Prepared:	June 10, 2012
Trade Name:	PMT Bone Screws
Common Name:	Bone Screw
Device Classification Regulation:	21 CFR 888.3040 – Class II
Device Product Code & Panel:	HWC: Screw, Fixation Bone 87, Orthopedics
Predicate Device:	Wright Compression Screws (K082320) ORTHOLOC Bone Screws (K112772)

Device Information

A. Intended Use

The PMT Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation appropriate for the size of the device. Screws are intended for single use only.

B. Device Description

The design features of the PMT Bone Screws are described below.

- Manufactured from Titanium Alloy
- Available headed or headless
- Available in various diameters and lengths

C. Substantial Equivalence Information

The design features, material, and indications for use of the PMT Bone Screws are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the PMT Bone Screws is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room—WO66-G609
Silver Spring, MD 20993-0002

SEP 27 2012

Providence Medical Technology, Incorporation
% Mr. Glen Mangseth
Quality Systems Manager
201 Spear Street, Suite 1310
San Francisco, California 94105

Re: K121713

Trade/Device Name: PMT Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 20, 2012
Received: August 20, 2012

Dear Mr. Mangseth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

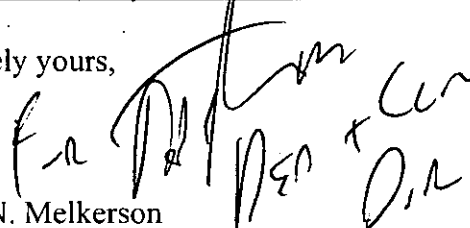
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a large, stylized flourish extending from the end of the signature.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use Statement**Indications for Use Form (Text Version)****Indications for Use**

510(k) Number (if known): _____

Device Name: PMT Bone Screws

Indications for Use:

PMT Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Prescription Use X
(Part 21 CFR 801 Subpart D)

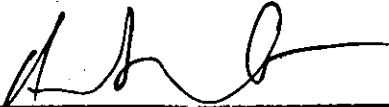
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121713